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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/719,868

11/21/2003

Chengrong Wang

DCS-9082

3058

34500

7590

05/30/2006

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EXAMINER

CEPERLEY, MARY

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,868	WANG ET AL.	
	Examiner	Art Unit	
	Mary (Molly) E. Ceperley	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2) Although specific claims may be discussed in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

3) Claim 6 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims do not correspond with the written description of the invention as set forth in the specification. The formula of claim 6 corresponds to the formula of Figure 2 of the reference wherein the variables R and R' are defined in paragraph [0012] of the specification. The description of paragraph [0012] states that R and R' can be "alkyl or allyl groups from C1 to C25...or aromatic groups with or without substitution". The definition of the variables R and R1 in claim 6, however, inconsistently states that R and R' (sic) are selected from the alternative definitions "alkyl, aryl, allyl, carbonyl,...or carbamate functional group"; thus, for example, R and R' in claim 6 can be "sulfate" or "phosphate" *per se* which are not attached to any "alkyl or allyl" group as required by the description of the specification. The language of claim 6 is not the same as or equivalent to the description of paragraph [0012] of the specification wherein "the alkyl, allyl or aromatic group may contain other functional groups such as ester, ether, ...phosphonate groups".

4) Claims 6 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the

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specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There is no enablement present in the specification for the preparation of the compounds of claim 6 wherein R and R' are not "alkyl", "allyl" or "aromatic groups" as defined in paragraph [0012] of the specification, i.e. there is no enablement for compounds wherein R and R' are defined, for example, as "carbonyl" (a non-terminal group) or "phosphonate". The term "contains" requires only that the compound "contain" the recited group; *no other moiety* is required to be "contained" in the definitions of R and R'. There is clearly no enablement present in the specification for the preparation and use of the claim 6 compounds "containing" solely moieties such as the defined functional groups (i.e. "carbonyl,...carbamate functional groups").

5) Claims 6-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 6 is indefinite in the use of the word "contains". The term implies that other moieties are present in the structure *in addition to* the recited group (e.g. "alkyl"). The exact structure of a compound which "contains" the recited group, as well as other undefined moieties, cannot be determined.

b) The use of the term "functional group" in the definitions of R and R' renders claim 6 indefinite and confusing. While the terms "carboxylate, amide ester,...carbamate" are conventional "functional groups" (i.e. reactive groups), "alkyl", "aryl", "allyl" and "carbonyl" groups are not conventional reactive "functional groups".

c) The term R" used in the formula definition in claim 6 is inconsistent with the designation R' which appears in the formula.

d) In claims 7 and 9, the first line after the formula, the term "R is" incorrectly appears twice.

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e) Claims 7 and 9 are still incomplete and confusing for the reasons stated in paragraphs **5)g)** and **h)** of the September 15, 2006 Office action. These rejections could be overcome by changing the term "detecting the receptor-pharmaceutical...of the pharmaceutical " to "detecting the receptor-pharmaceutical *complex* and *correlating the detection with* the amount of the pharmaceutical *in the sample*". A similar change in wording is needed for claim 12.

f) For claim 6, the same problems addressed in paragraph **5)a)** of the September 15, 2005 Office action still pertain. See also the statements regarding the terms such as "carbonyl" in paragraph **5)a)**.

g) The rejections of paragraphs **5)b)** and **5)g)** of the September Office action still apply. Applicants have not specifically addressed these rejections which have not been overcome by the amendments to the claims.

6) Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al (US 6,338,946).

The reference is applied for its description of compounds which anticipate the compounds recited in claim 6 (see paragraph **8)** of the September 15, 2005 Office action). The reference further describes these compounds in combination with a buffer solution as recited in claim 6 of this application; this disclosure anticipates the two-component (compound plus buffer) "assay releasing reagent" of claim 6 of this application. The concentration of the compound of claim 6 in the buffer which comprises an "effective amount" appears to be encompassed by the buffered solution of the reference. See Kobayashi et al: col. 9, lines 20-22. Applicants do not dispute the fact that the reference describes compounds which are included in claim 6 of this application (March 20, 2006 Remarks, page 8 of 8). The "for use in" limitation of claim 6 does not constitute a limitation on the composition *per se* (for example, a composition comprising aspirin dissolved in water is still aspirin dissolved in water independent of how the composition may be used).

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7) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8) Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over each of Grassberger et al (US 5,665,727), FUJISAWA (WO 91/02736), FUJISAWA (WO 91/17754) or FUJISAWA (WO 92/00313).

Each of the references describes compounds which anticipate the compounds of claim 6 of this application. Applicants have not disputed this fact (March 20, 2006 Remarks, page 8 of 8). The references further describe these compounds as components of a variety of pharmaceutical compositions. See Grassberger et al: col. 2, lines 15-24; FUJISAWA (WO 91/02736): page 11, lines 9-28; FUJISAWA (WO 91/17754): page 9, lines 9-32; FUJISAWA (WO 92/00313): page 22, lines 1-21. From this description of a variety of types of pharmaceutical compositions containing FK506-type compounds, one skilled in the art would expect and consider it obvious that the compositions could be routinely modified to contain well known diluents such as buffers, as claimed, with the expectation of obtaining similarly useful pharmaceutical compositions. Again, the method of use limitation is not a limitation on the composition *per se*. See paragraph **6)** above.

9) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

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action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 18, 2006


Mary (Molly) E. Ceperley
Primary Examiner
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